



AUG 3 1998

K973243

Diagnostic Systems Laboratories, Inc.  
445 Medical Center Boulevard  
Webster Texas 77598-4217 USA  
Tel 281.332.9678  
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Customer Assistance Center  
Tel 800.231.7970  
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## SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-9700 PSA ELISA Kit  
Classification Name: Enzyme-linked Immunosorbent Assay for PSA  
Analyte Code and Name: Prostate Specific Antigen  
Regulatory Class: II

Submitter: John Class  
Diagnostic Systems Laboratories, Inc.  
445 Medical Center Boulevard  
Webster, Texas 77598  
Phone: 281-332-9678

Date: July 28, 1998

The DSL 10-9700 PSA ELISA kit was developed for the quantitative measurement of Total PSA in human serum. The ELISA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the microtiter plate wells, the other antibody is conjugated to the enzyme horseradish peroxidase for detection. The analyte present is bound by both the antibodies to form a "sandwich" complex. Unbound materials are removed by decanting and washing the microtiter plate. The resultant is analyzed in a spectrophotometer for absorbance. The amount of bound PSA is directly proportional to the concentration of the PSA present in the sample.

The DSL PSA ELISA assay is intended for the quantitative determination of Total PSA in human serum to aid in the management (monitoring the reoccurrence of prostate cancer) of prostate cancer patients.

The DSL 10-9700 PSA ELISA is substantially equivalent to the DPC IMMULITE PSA assay.

To demonstrate substantial equivalence between the two assays, human serum samples (n = 193) were collected and assayed using both methods. Samples were chosen based on expected PSA levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation  $Y = 1.11[\text{DPC IMMULITE}] + 0.77$  with a correlation coefficient of  $(r) = 0.96$ .



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 3 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. John Class  
Diagnostic Systems Laboratories, Inc.  
445 Medical Center Boulevard  
Webster, Texas 77598

Re: K973243/S2  
Trade Name: Active™ PSA ELISA (DSL-10-9700)  
Regulatory Class: II  
Product Code: LTJ  
Dated: June 9, 1998  
Received: June 9, 1998

Dear Mr. Class:

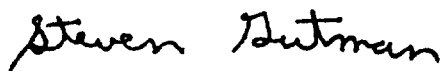
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, reading "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

29 Jul 93 0 04

510(k) Number (if known): K973243

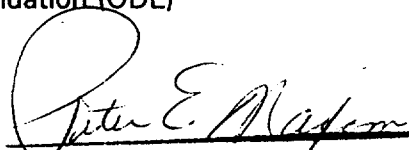
Device Name: Active™ PSA ELISA

Indications For Use:

The DSL-9700 Active™ PSA Enzyme-Linked Immunosorbent Assay (ELISA) Kit provides materials for the quantitative measurement of Total PSA in human serum to aid in the management (monitoring the reoccurrence of prostate cancer) of prostate cancer patients. This assay is intended for *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973243

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_